

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Interstate Movement
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

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|-------------------------|---|----------------------------|-------------------|
| PERMITTEE NAME: | Caleb Adams | PERMIT NUMBER: | P526P-20-00174 |
| ORGANIZATION: | COASTBIO | APPLICATION NUMBER: | P526-190626-006 |
| ADDRESS: | 3300 Maplethorpe Lane Soquel, CA 95073 | FACILITY NUMBER: | N/A |
| MAILING ADDRESS: | 3300 Maplethorpe Lane Soquel, CA 95073 | HAND CARRY: | No |
| PHONE: | 805-550-1276 | DATE ISSUED: | 01/10/2020 |
| FAX: | | EXPIRES: | 01/10/2023 |
| DESTINATION: | COASTBIO, Incorporated, 3300 Maplethorpe Lane, Soquel, CA 95073 | | |
| RELEASE: | No | | |

Under the conditions specified, this permit authorizes the following:

| <u>Regulated Article</u> | <u>Life Stage(s)</u> | <u>Intended Use</u> | <u>Shipment Origins</u> | <u>Originally Collected</u> | <u>Culture Designation</u> |
|----------------------------|----------------------|---------------------|-----------------------------|---|--------------------------------|
| Azospirillum brasilense | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Azotobacter chroococcum | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus amyloliquefaciens | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus azotofixans | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus coagulans | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus licheniformis | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus megaterium | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus mojavensis | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus polymyxa | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus pumilus | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |
| Bacillus subtilis | Any | Research - Lab | WI | Originally Collected from Foreign Locations | |

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PPQ HEADQUARTER OFFICIAL VIA EPERMITS.



Carl Schulze

DATE

01/10/2020

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

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|---------------------------|-----|----------------|----|---|
| Paenibacillus azotofixans | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Pseudomonas putida | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Streptomyces griseus | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Streptomyces lydicus | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Trichoderma asperellum | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Trichoderma harzianum | Any | Research - Lab | WI | Originally Collected from Foreign Locations |
| Trichoderma viride | Any | Research - Lab | WI | Originally Collected from Foreign Locations |

PERMIT GUIDANCE


- 1) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 2) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_and_products.shtml
- 3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 4) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 5) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS issues this permit to Caleb Adams with COASTBIO in Soquel, California. This permit authorizes the interstate movement of the listed organisms from Wisconsin to California.

This permit authorizes use of the regulated organisms for production and packaging activities only. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a

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valid PPQ526 permit for receipt of such materials/organisms.

1.
 - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - The permit number or a copy of the permit must accompany the shipment.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,

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- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.

- This permit does not authorize movement or use of organisms listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. For a complete list of Select Agents please visit: <https://www.selectagents.gov/selectagentsandtoxinslist.html>
Select agents include: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*), *Ralstonia solanacearum*, *Rathayibacter toxicus*, *Sclerophthora rayssiae*, *Synchytrium endobioticum*, *Xanthomonas oryzae*, *Bacillus anthracis*, *Brucella abortus*, *Brucella melitensis*, *Brucella suis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*.
- All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to adhere to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

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5. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
6. Upon receipt, all packages must be opened within a Class II or III biosafety cabinet, or within a still-air environment (e.g. a transfer hood with the air turned off), located within the facilities at the destination address identified above to prevent the potential dissemination of the package contents. Cultures must be in a sealed container during transport to or within the permit holder's assigned research facilities.
7. All production and packaging activities must occur at the destination location identified above. This location must have facilities that are adequate to prevent the unauthorized dissemination of the regulated live organisms received under this permit. Access to this facility must not be accessible to the general public.
8. Regulated materials/organisms must be stored or maintained in an area that is not accessible to the general public.
9. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, and the date the isolate was received. These records must be made available to Federal and State regulators upon request.
10. • DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination:

1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in a minimum of a final concentration of 0.525 percent sodium hypochlorite (1 part fresh household bleach to 9 parts

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water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR


The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the *Geobacillus stearothermophilus* and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

11. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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